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510(k) SUMMARY

OCT - 3 2011

Submitter's Information

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Date Summary was Prepared: October 4, 2011

Device Information

Proprietary Name:	Excellagen
Common Name:	Collagen Wound Dressing
Classification Name:	Dressing, Wound, Collagen
Product Code:	KGN

Predicate Devices

Integra Flowable Wound Matrix, K072113
Stimulen Collagen, K030774
Medifil gel, K910944
HyCure Hydrolyzed Collagen, K955506
Collatek Powder, K012990
HeliDerm Collagen Wound Dressing, K990086

Device Description

Excellagen is a wound care device composed of formulated, 2.6% (26 mg/mL) fibrillar bovine dermal collagen (Type I) that is topically applied directly to the wound surface. Excellagen is packaged as single-use units to ensure safety and provide for easy topical application. The device is tested for sterility in accordance with USP<71>. Excellagen is supplied in one of two kit configurations. One kit configuration consists of four single-use 1.0 cc syringes, each containing 0.5 cc of 2.6% (26 mg/mL) formulated collagen, and four single-use sterile flexible applicators. This kit can be used for smaller wounds. The

second kit configuration consists of one single-use 10.0 cc syringe containing 4.0 cc of 2.6% (26 mg/mL) formulated collagen, and one single-use sterile flexible applicator. This kit can be used for larger or tunneling/undermined wounds. Excellagen is stored at standard refrigeration temperature (2-8°C).

During manufacture, the collagen component of Excellagen is purified using a specialized process that eliminates impurities (including endotoxins), and removes denatured molecules and collagen fragments. Excellagen consists almost exclusively of high molecular weight, intact, fibrillar collagen and is formulated at a concentration of 2.6% (26 mg/mL) in an isotonic buffer with protein stabilizing agents.

Intended Use

Excellagen is a wound care device intended for the management of wounds including partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) and draining wounds. This device is packaged for one-time use.

Excellagen is contraindicated for individuals with a known sensitivity to products of bovine origin.

Technological Characteristics Compared to Predicates

	Excellagen	Predicates					
		Integra Flowable	Stimulen	Medifil Gel	HyCure	Collatek	Heliderm
510(k) Number	pending	K072113	K030774	K910994	K955506	K012990	K990086
Material	Type I collagen	Type I collagen (x-linked + GAGs)	Soluble modified collagen	Type I collagen	Type I collagen (96%)	Type I collagen	Type I collagen
Source	Bovine	Bovine	Bovine	Bovine	Bovine	Bovine	Bovine
Form	Fibrillar Gel	Hydrated Granules	Gel	Collagen Suspension	Powder	Powder	Microfibrils
Biodegradable	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Biocompatible	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Sterile	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Storage	Refrigerated 2-8°C	Room Temp	Room Temp	Refrigerated <16°C	Room Temp	Not available	Room Temp

Safety
The safety of Excellagen has been established based on standard non-clinical *in vitro* (cytotoxicity) and *in vivo* (sensitization and intracutaneous reactivity) biocompatibility testing in accordance with ISO 10993-1. Excellagen was found to be biocompatible in all tests.

Substantial Equivalence
Excellagen is substantially equivalent in function (wound management), materials (bovine Type I collagen), intended use (direct topical application to dermal wounds) and safety profile (biodegradable and biocompatible, passed sterility testing in accordance with USP<71>) to the following products which have been cleared to market under Section 510(k) premarket notifications: Integra Flowable Wound Matrix (K072113), Stimulen Collagen (K030774) Medifil gel (K910944), HyCure Hydrolyzed Collagen (K955506), Collatek Powder (K012990), HeliDerm Collagen Wound Dressing (K990086).

Conclusion
Excellagen is safe under the proposed conditions of use and substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Tissue Repair Company
% Lois Chandler, Ph.D.
12255 El Camino Real, Suite 250
San Diego, California 92130

OCT - 3 2011

Re: K110318
Trade/Device Name: Excellagen
Regulatory Class: Unclassified
Product Code: KGN
Dated: September 26, 2011
Received: September 27, 2011

Dear Dr. Chandler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110318

Device Name: Excellagen

Indications for Use:
Excellagen is indicated for the management of wounds including partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) and draining wounds. This device is packaged for one-time use.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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